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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,302	10/16/2006	Jeremy Fairbank	UDL-121US	3386
23122	7590	11/12/2008		
RATNERPRESTIA P.O. BOX 980 VALLEY FORGE, PA 19482			EXAMINER PATTON, AMANDA K	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/568,302	<b>Applicant(s)</b> FAIRBANK ET AL.	
	<b>Examiner</b> Amanda Patton	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 9-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

Applicant's amendment dated July 30, 2008 is acknowledged. Currently claims 1-6 and 9-27 are pending in this application.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 9-11, 14-16, and 18-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woods (USPN 6,609,032) in view of Daignault Jr. et al. (USPN 6,748,276).

Regarding **claims 1-2, and 4** Woods teaches an apparatus for stimulation of the human body, comprising:

- an array of stimulator elements (e.g. array of electrodes 23) arranged to be operated in a plurality of stimulator activation zone configurations to effect localized stimulation of a human body corresponding to each of the activation zone configurations (e.g. the possible usable combination of the electrodes in electrode array 33 as stated in Col. 9, lines 37-54, used to adjust the neurostimulator settings for each patient); and
- a user interface device (e.g. joystick programmer system 10, including display 16 which includes a screen) including a selectable array of independent input zones (e.g. the independent input zones 160 of Figure 12A) relatable to a respective group of stimulator

elements (e.g. spinal cord stimulator 20) permitting the user to relate each input zone of the interface device to the respective stimulator element;

- wherein the apparatus is operable in a mode in which the patient is provided stimulation independent of their choice and then requested to indicate, on the display using the stylus, where they feel the stimulation (e.g. Figure 12G).

Woods does not expressly disclose each input zone corresponding to a respective independent stimulator element. Dagnault discloses that it was known in the art to use any number of stimulator elements in a stimulation setting related to an independent input zone (e.g. a stimulation setting that, as any number of electrodes can be active, can include a single active electrode and independent input zones as shown as element 210 in Figure 9A; Col. 1, line 45 - Col. 2, line 35). It would have been obvious to use the single active electrode related to an independent input zone of Dagnault in the system of Woods, since such a modification would provide the system with a reliable way to relate a single active electrode with a related independent input zone for providing the predictable results of an easy way to optimize individual user stimulation.

Regarding **claim 3**, Woods additionally teaches an interface device that includes an interface zone array corresponding to the positional spacing of activation zones of the array of stimulator elements (e.g. Figures 4, 12D, and 12G).

Regarding **claims 5-6**, Woods additionally teaches an apparatus operable in a second mode in which user input to the interface device determines the activation zone configuration of the array of stimulator elements wherein the interface device includes an input zone array

corresponding spatially to the activation zone configuration of the array of stimulator elements (e.g. Figure 12D).

Regarding **claim 9**, Woods additionally teaches switching between the two modes (e.g. as shown in Figures 12D and 12G).

Regarding **claim 10**, Woods additionally teaches an apparatus including a means for storing results data (e.g. memory 54 as shown in Figure 2).

Regarding **claim 11**, Woods additionally teaches an apparatus wherein the array of stimulator elements (e.g. electrodes 33) are carried in a predetermined spatial relationship on a support member (e.g. electrode array 23; Figures 6A-6C).

Regarding **claim 14**, Woods additionally teaches an apparatus wherein the support member (e.g. electrode array 23) comprises an implant for insertion in the body (e.g. connected to pulse generator 20' as shown in Figure 6C).

Regarding **claim 15**, Woods additionally teaches an apparatus wherein the support member (e.g. electrode array 23" of Figure 6C) includes space in between the electrodes, which can be considered barrier zones, in order to maximize attenuation beyond the locality of the stimulator elements.

Regarding **claim 16**, Woods additionally teaches an apparatus wherein the stimulator elements are arranged grid-wise in rows and columns (e.g. Figure 5B).

Regarding **claims 18 and 19**, Woods additionally teaches an apparatus wherein the stimulation intensity (e.g. pulse amplitude) and the activation duration (pulse width) of the stimulator elements can be varied (e.g. Figures 12C, and 12E-12F).

Regarding **claim 20**, Woods additionally teaches an apparatus including a control arrangement (e.g. stimulator processor 52) to control the interaction between the interface device (e.g. programming system 10) and the stimulator element array (e.g. electrode array 23, all as shown in Figure 2).

Regarding **claim 21 and 22**, Woods additionally teaches an apparatus that includes data transmitting means (e.g. coil 28 of the programming device and coil 62 of the implantable stimulator) whereby results from the apparatus can be downloaded to a processor (e.g. stimulator processor 52) by a wireless connection, wherein the processor is part of the programming system 10 and in one embodiment as shown in Figure 1A is a laptop.

Regarding **claim 23-27**, Woods additionally teaches that the apparatus above can also be used with external stimulator elements (e.g. Col. 5, lines 10-15).

Claims 12-13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woods and Daignault in view of Brannon (US Pat. 6,193,678, hereafter referred to as Brannon).

Regarding **claim 12**, Neither Woods nor Daignault disclose a support member comprising a garment to be worn by the user. Brannon teaches it is known in the art to have a stimulation system that includes a vest 12 containing a plurality of vibratory units 18 (Figure 2 and Col. 3, lines 55-67). It would have been obvious to one of ordinary skill at the time the invention was made to modify the system of Woods and Daignault to include the vest and vibratory units of Brannon in order to provide an external electrode array for providing the predictable results of a temporary stimulatory device that can be removed with relatively little effort when not in use.

Regarding **claim 13**, Woods, Daignault, and Brannon do not teach a garment comprising a corset. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the system as taught by Woods, Daignault, and Brannon with a corset, because Applicant has not disclosed that the corset provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the vest as taught by Brannon, because it provides an support for an external electrode array and the choice of a corset appears to be an arbitrary design consideration which fails to patentably distinguish over Woods, Daignault, and Brannon. Therefore, it would have been an obvious matter of design choice to modify Woods, Daignault, and Brannon to obtain the invention as specified in the claims.

Regarding **claim 17**, Woods and Daignault discloses the claimed invention except stimulator elements that comprise vibrator devices. Brannon, however, teaches that it is known in the art to use vibratory units 18 (as shown in Figure 2 and Col. 3, lines 55-67) that act as stimulator elements. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Woods and Daignault to include the vibratory units of Brannon, since such a modification would provide a the system with a vibratory electrode array for providing the predictable results of a device capable of provide more diverse treatment options.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-6 and 9-27 have been considered but are moot in view of the new ground(s) of rejection as necessitated by amendment.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Patton whose telephone number is (571) 270-1912. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AKP/  
Examiner, Art Unit 3762

/George R Evanisko/  
Primary Examiner, Art Unit 3762